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P/546-279 REISSUE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Patent Application of:

William STERN

Date: February 12, 2008

Reissue Serial No.: 10/774,358

Confirmation No.: 8408

Reissue Appln. Filed: February 5, 2004

Group Art Unit: 1616

Reissue of U.S. Patent No.: 6,440,392

Examiner: Mina Haghigian

Issued: August 27, 2002

For: NASAL CALCITONIN FORMULATION

Mail Stop Reissue

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

SUMMARY OF EXAMINER INTERVIEW
PURSUANT TO M.P.E.P. §713.04

Applicant submits this interview summary in accordance with M.P.E.P. §713.04. The Examiner is thanked for her interview summary mailed January 14, 2008, with which Applicant is in substantial agreement.

A personal interview was held with Examiner Mina Haghigian and SPE Johann Richter on January 8, 2008. Participating in the interview, on behalf of the applicant, were inventor William Stern and applicant's attorney, William O. Gray, III (Reg. No. 30,944).

All claims and all references cited in the most recent office action were discussed generally. Applicant's attorney noted that all claims recited a concentration of citrate (citric acid and/or citric acid salt) that is believed to provide unexpected advantages relative to the prior art cited in the most recent office action. In particular, it was pointed out that unexpected enhancement of shelf stability results from keeping citrate levels low.

Dr. Stern discussed how elevated-temperature data submitted in his previously-filed declaration (filed in October, 2007) showed an unexpected increase in degradation of the salmon calcitonin active agent at citrate concentrations higher than those permitted by the present claims.

It was noted that it is common in the pharmaceutical industry to apply the Arrhenius equation to degradation data obtained for formulations stored at elevated temperatures for short time periods to predict degradation (and hence shelf stability) for such formulations when stored at lower temperatures for longer time periods. SPE Richter asked Dr. Stern to provide Arrhenius graphs to better illustrate that point. Examiner Haghigatian indicated that, upon receipt of the Arrhenius graphs, she and SPE Richter would further discuss the evidence of unexpected results.

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Mail Stop Reissue, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on February 12, 2008:

William O. Gray, III
Name of applicant, assignee or
Registered Representative


Signature

February 12, 2008
Date of Signature

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Respectfully submitted,


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